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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,179	03/12/2004	Manoj Kumar	DOC0057PA/DC5074/GC792-4	8989

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,179	KUMAR ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-11 and 13-34* is/are pending in the application.

4a) Of the above claim(s) *5-7,10,11,20-26,28-30,32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,9,13-19,27,31 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments/Amendments

Applicant's arguments and amendments filed November 20, 2006 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

The terminal disclaimers filed on November 20, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date(s) of 11/351,721, 10/845,775 and 10/939,036 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Claims 1, 3-7, 9-11, 13-33 and new claim 34 are pending. Claims 5-7, 10, 11, 20-26, 28-30, 32 and 33 remain withdrawn for the reasons of record.

Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitations of new claim 34 have been incorporated into claim 1 as presented in the amendment, and thus it is not further limiting.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 9, 13-19, 27, 31 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record and those set forth below. The claim(s) contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)." Further, the MPEP states, "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

In the instant case, the newly added proviso in claim 1 that at least one of x, x' and x'' is not zero is not supported by express, implicit, or inherent disclosure. While the specification provides examples of peptides embraced by the broad claims, the peptides could be parsed in any of a myriad of ways, and nothing would lead one to specifically identify that at least one was not zero.

Claims 1, 3, 4, 9, 13-19, 27, 31 and 34 remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional

characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. While all of the factors are considered, a sufficient amount for a prima facie case are discussed below.

Respectfully, Applicant states that the recitation of 'about' in, e.g. "about 3" has been removed; however it remains in the claims for the other variables, e.g. B, B', T and T'.

Applicant asserts that the examiner has reinstated the 112 1st paragraph rejection, once considered persuasive, without providing an explanation. Applicant indicates that the traversal is essentially those which were previously considered 'persuasive'.

Respectfully, the rejection was reintroduced because, upon further reconsideration, the examiner determined the rejection was improperly withdrawn in a previous action.

Applicant argues that the written description requirement is satisfied ant that the claimed compounds are RSPPs that have "a well-defined chemical structure as explicitly recited in all claims." (page 11). Applicant disagrees that the recitation of A, A' and A" *require* at least 90 repeating a, A' and A" units. Applicant argues that making RSPPs would be apparent to a person of ordinary skill in the art "once the desired characteristics have been determined." (page 12). Applicant argues that, "A person of ordinary skill in the formulation arts, however, will readily recognize from the materials provided in the written description how to select and how to make the claimed RSPPs." (page 12).

Applicant argues that written description requires either disclosure of a representative number of species or "recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." (pages 12-13). Applicant argues that this aspect is satisfied.

Respectfully, the examiner disagrees. The alleged "structural feature common to members of the genus" is nothing more than a broad generic with no description of any particular member or species, and defines an infinite number of peptides are within the genus. In fact, the definition is so broad, that any peptide within the disputed length could be parsed such that it reads upon the instant claims, so long as it is in an appropriate composition. The peptides within this alleged structural feature common to the genus is, indeed, infinite. Each subscript, y, x, b, x', b', x" and y" can be zero, with the only caveat that at least one of x, x' and x" is not zero and there are "at least 30 amino acids in A, A' and A" individual repeating sequence units." Within claim 1, not a single amino acid is specifically defined. Furthermore, the claim requires specific function be imparted in the peptide- the benefit to the surface of the skin, hair, nails or oral cavity, and the claims and disclosure do not set forth a sufficient number of examples of such peptides within the vast genus to show Applicant was in possession of the genus as claimed.

In the instant case, the claims are drawn to personal care compositions that are "adapted to provide at least one benefit to the surface" to which it is applied, comprising an effective amount of a repeat sequence protein polymer (RSPP) of the formula:

$T_y[(A_n)_x(B)_b(A'_{n'})_{x'}(B')_{b'}(A''_{n''})_{x''}]_iT'_{y'}$.

T and T′ are present or absent (y and y′= 0 or 1) and each comprise an amino acid sequence of about 1 to about 100 amino acids

A, A′, A′′ are present or absent (x, x′ and x′′ = 0 or 1), where at least 1 is present and each comprises 3 to 30 amino acids and each is repeated 2 to 250 times (n, n′ and n′′=2 to 250).

B and B′ are about 4 to about 50 amino acids and repeated 0 to 3 times (b and b′= 0 to 3).

The peptide bounded by T and T′, which if present (y, y'= 0 or 1), is one to 100 amino acids.

The personal care composition is a product for application to the skin, hair, nails, oral cavity and related membranes for the purposes of improving, cleaning, beautifying, therapeutically treating, caring for these surfaces and membranes (paragraph [0015]). This limitation has been incorporated into the claims.

"An effective amount refers to the amount of [an RSPP] which is added to a personal care composition to provide the composition with a desired characteristic or characteristics." (paragraph [0016]).

(1) Level of skill and knowledge in the art:

The synthesis of peptides is well known in the art, however the synthesis of an infinite number of peptides with any of a myriad of "desired characteristic(s)" and compositions which are used in a myriad of functions embraced by the claims is beyond that the skill of the artisan, particularly since the intended use (e.g. application to the hair for cleaning, or application to the skin for improving the surface, etc.) and the 'desired characteristics' are undefined or unable to be correlated with a particular structure.

(2) Partial structure:

The claims recite the structure above and that the RSPP can comprise, e.g. collagen, elastin, etc. which has now been eliminated from the claims (claim 2 has been cancelled), and the structure is bound by no specific structural limitations beyond length of the repeat unit.

Furthermore, Applicant's arguments assert that it is clear that minimum peptide length must be at least 30 (page 4, 1st paragraph), while the claim infers that it must be at least 90 (x, x′

and x'' are varied "to provide for at least 30 amino acids in the A, A', A'' individual repeating sequence units" (e.g. claim 1). One interpretation is that each has at least 30 amino acids (30 + 30 + 30 = 90). Applicant argues that this inference is incorrect, however it is noted that this is merely one interpretation of the broad claims.

The specification provides examples of repeating sequence units and the sources of some repeat units, however the specification does not provide a sufficient number of species to describe the whole genus with the 'desired characteristic(s)'.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The composition must comprise a peptide embraced by the genus and the composition must be "adapted to provide at least one benefit to the surface of the skin, hair, nails or oral cavity", where the benefit desired remains undefined.

(5) Method of making the claimed invention:

The specification provides the source of some individual repeating sequence units and provides methods of making peptides and compositions; however the specification fails to adequately describe which compounds are to be made to obtain the specific desired result.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 1 is a broad generic, with respect to all possible compounds encompassed by the claims, and the compositions comprising them. The possible structural variations are limitless to any class of peptide comprising 'personal care composition'.

It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the

sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus, as the few examples in the specification are insufficient to describe all of the peptide compositions embraced by the claims with any of an infinite number of benefits.

While having written description of compositions comprising SEQ ID NO:19 and the various SELPs identified in the specification tables and/or examples, the specification is void of a sufficient number of examples to describe the infinite number of peptide compositions within the genus with the requisite activity.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 9, 13, 14, 31 and 34 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by WOLFINBARGER (US PGPUB 2002/0147154 A1).

Applicant argues that, "the examiner has seriously misplaced the burden of proof here. It is the Patent Office's burden to establish that the prior art anticipates a claim" (page 14). Respectfully, the examiner disagrees. The examiner set forth a proper case of anticipation, and as stated previously, the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Here, the burden was properly shifted to Applicant, and Applicant has not shown any evidence to rebut the rejection set forth by the examiner.

The claims are drawn to repeat sequence protein polymers.

Wolfinbarger teaches a cosmetic composition, comprising marine invertebrate type V telopeptide collagen (claim 1), where the collagen is present in an amount of from 0.001 wt % to 30 wt % (claim 4), 0.1 wt % to 10 wt % (claim 5), or 0.2 wt % to 5 wt % (claim 6).

Wolfinbarger teaches a cream rinse hair-conditioner with collagen gelatin solution at 0.2 w/w % (Example 10, page 9). The cream rinse comprises carriers and excipients, e.g., cetyl alcohol, dimethicone, xanthan gum, water, and stearic acid. (Example 10).

The instant specification states, "Specifically, there are more than six hundred repeating amino acid sequence units known to exist in biological systems. For example, well known

proteins containing repeating amino acid sequence units include abductin, elastin, byssus, flagelliform silk, dragline silk, gluten high molecular weight (HMW) subunit, titin, fibronectin, leminin, and collagen. Individual repeating amino acid sequence units of particular interest include units found in silk-, elastin-, collagen-, abductin-, byssus-, gluten-, titin-. extensin-, and fibronectin-like proteins... Collagen-like proteins comprise a repeating sequence unit of G-X-X1, wherein X comprises any amino acid, X1 comprises any amino acid, often proline or hydroxy-proline (SEQ ID NO:20)."(page 4, Specification).

Thus, any collagen meets the limitations of these claims regardless of the source, as the specification does not indicate that only one specific type from one specific source is the collagen that has a specific sequence in any RSPP. Additionally, application of the composition comprising collagen would necessarily provide a benefit to the surface to which it was applied.

Furthermore, Applicant has not provided any evidence to prove the type V telopeptide collagen is not the same as what is instantly claimed, but rather argues that, "Wolfinbarger fails to disclose any repeat sequence protein polymers that would anticipate the formula recited" (page 9). As the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1, 3, 4, 13, 14, 16-19, 27, 31 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by FOSSATI (US Patent 5,916,542).

Fossati teaches an anti-aging, anti-wrinkle and protective cream comprising various elements, including 1% collagen and 2% soluble elastin (claim 8) in a carrier, emulsifier and preserving agent mixture with 3% of an antisolar mixture and 2% placenta.

As stated *supra*, the instant specification states, "Specifically, there are more than six hundred repeating amino acid sequence units known to exist in biological systems. For example, well known proteins containing repeating amino acid sequence units include abductin, elastin, byssus, flagelliform silk, dragline silk, gluten high molecular weight (HMW) subunit, titin, fibronectin, leminin, and collagen. Individual repeating amino acid sequence units of particular interest include units found in silk-, elastin-, collagen-, abductin-, byssus-, gluten-, titin-. extensin-, and fibronectin-like proteins... Collagen-like proteins comprise a repeating sequence unit of G-X-X1, wherein X comprises any amino acid, X1 comprises any amino acid, often proline or hydroxy-proline (SEQ ID NO:20)."(page 4, Specification).

Thus, collagen and/or elastin in a cream meet the instantly claimed limitations, as collagen and/or elastin would necessarily have the requisite repeat pattern as claimed. As above, because the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 5-7, 10, 11, 20-26, 28-30, 32 and 33 drawn to an invention nonelected without traverse on December 1, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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